

**REQUEST FOR EXTENSION OF TIME**

Applicants request a one-month extension of time to respond to the restriction requirement which was due June 21, 2002, up to and including July 21, 2002. Since July 21, 2002 falls on a Sunday, submission of the response on Monday, July 22, 2002, the first following business day of the United States Patent and Trademark Office, is considered timely.

The Commissioner is authorized to charge the small entity fee due in the matter to Deposit Account No. 23-1703.

**REMARKS**

Applicant respectfully request reconsideration of the Restriction Requirement. Accordingly, the immunogenic composition of claims 35-52 comprising an aqueous immunogen and pharmaceutically acceptable oily vehicle wherein the immunogen comprises an immunomimic peptide conjugated to the an immunogenic carrier has been restricted to Group I claims 35-52 directed to a G17 immunomimic peptide, Group II claims 35-52 directed to a G34 immunomimic peptide, and Group III claim 35-52 directed to a GnRH immunomimic peptide.

The Examiner alleges that the three claim groups are different subject matter by their structure, function, and effects. Furthermore, the Examiner requires election of a specific immunogenic composition comprising (1) a specific squalene oily vehicle from claim 39, or (2) a specific squalene oily vehicle of claim 40. The vehicles allegedly differ by their structures and properties.

Applicants provisionally elect, with traverse, Group I claims 35-52 directed to a composition comprising an aqueous immunogen and a pharmaceutically acceptable oily vehicle wherein the immunogen comprises a gastrin-17 (G17) conjugated to an immunogenic carrier optionally linked through a spacer peptide, and method for formulating said composition.

Further as required, Applicants provisionally elect with traverse a specific oily vehicle from the group recited in claim 40, more particularly Montanide ISA 703.

In accordance with the provisional election of Group I and species, the invention provisionally elected is therefore readable on claims 35, 36, 38, 40, 41, 43, 44, and 48-52. The Applicants reserve the right to prosecute the nonelected subject matter in a divisional application.

Contrary to the Examiner's allegation, the claimed invention of the claims 35-52 cannot be divided into Groups I, II, and III. In fact, the claimed invention clearly pertains to the immunogenic compositions which can surprisingly withstand at least 5 cycles of freezing and thawing from storage at temperatures of  $-18^{\circ}$ ,  $-23^{\circ}$  and  $-70^{\circ}$  (Table 7). Particular listed types of squalene/squalane products have been found to be stable in appearance or immunogenicity. No significant change in globule size distribution was observed after the 12 months of frozen storage of the emulsion (see Table 2). Moreover, there was no significant change in conjugate integrity or purity after 12 months of frozen storage.

Therefore, the surprising discovery of frozen storage stability is not related to the type of immunomimic peptide regardless of whether the antigenic target is G17, G34, or GnRH, as prepared in the co-assigned US 5,688,506 US 5,468,494, and US 5,023,077, which disclosures are incorporated in the Specification by reference (page 6, line 18).

All of the pharmaceutically acceptable oily vehicle species recited in claim 40 have been found suitable for stable frozen storage emulsions of the injectable immunogenic composition regardless of the immunogenic conjugate involved. If forced to choose a single species, Applicants have elected Montanide ISA 703. However, in traverse, Applicants assert that the other vehicles such as Montanide ISA 25, ISA 720 have been tested and found suitable as described in the Specification and shown in Table 7. The differences of structure and

physicochemical properties or mode of action as alleged by the Examiner are not disclosed in the instant Specification since the ingredients have been selected strictly on the basis of their effect on storage stability in the instant emulsions at suitable ratios of aqueous protein and emulsifiable ingredient.

Moreover, Applicants have not divided the claims on the basis of distinctly separate uses of squalane and squalene. On the contrary, the pharmaceutically amenable oily vehicles recited in claim 40 include mixtures of squalane and squalene, the ratios of which are not known as to theoretical relevance to the claimed storage stability when frozen and thawed repeatedly.

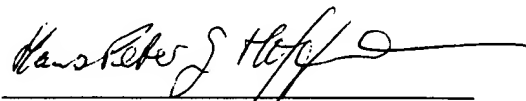
The Examiner in actuality has issued a restriction argument which potentially generates thirty-two divisional applications from one invention. Such action would place enormous financial strain on the inventors and increase the Office's cost of search and examination of the claimed subject matter commensurately.

Applicants therefore request withdrawal of the requirement to restrict the invention according to the Examiner's reading of the invention.

The Commissioner is authorized to charge any fees which may be due in connection with this response to Deposit Account No. 23-1703.

Dated: July 22, 2002

Respectfully submitted,



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